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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,293	ROORDA, WOUTER	
	Examin r	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 8-23, drawn to a method, classified in class 427, subclass 2.24.

II. Claim 7, drawn to a device, classified in class 623, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as applying the composition to the device in the absence of a fluid, avoiding the necessity of the evaporation step.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Cameron Kerrigan on 6/17/2002 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-6 and 8-23. Affirmation of this election must be made by applicant in replying to this Office action. Claim 7 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "warm" in claims 21-22 is a relative term.

In regard to claim 21 only, the phrase --the heated implantable device at a temperature above ambient temperature--, or the like, instead of "the warm implantable device" would be more clear in regards to antecedent basis.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaraman.

Jayaraman teaches a method of coating an implantable device comprising adjusting the temperature of the device to a temperature other than ambient temperature (col. 3, line

19 and 24) and then applying a coating substance to the device (col. 3, lines 33 and 54).

Regarding claim 2, the stent is metal (abstract).

Regarding claim 3, the adjustment comprises an increase in temperature, as taught above.

Regarding claim 4, Jayaraman teaches coating the stent with polymers and or active agents (col. 3, lines 53-60) in a container of fluid, followed by removal of the stent and subsequent drying. The coating agents of Jayaraman are inherently present in a solvent due to the drying requirement of his method.

12. Claims 1, 3-5, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fan et al.

Fan teaches applying a coating substance to an implantable device and adjusting the temperature of the device to a temperature other than ambient temperature (Examples 71-73, col. 16).

The temperature used in Fan is 75 degrees centigrade, which is an increase above ambient temperature, as required by claim 3.

Regarding claim 4, Fan teaches the coating substance to include a polymer in solution (Examples 6-9; col. 16, line 20).

Regarding claim 5, Fan teaches applying a fluid to an implantable device, followed by blowing preheated hot air onto the device to dry the device (col. 16, lines 20-30). The fluid/solvent of Fan is inherently evaporated in the drying process of Fan.

Regarding claim 11, the temperature of the gas of Fan lies within the range claimed by Applicant.

Regarding claim 14, Fan teaches coating with polymer in fluid as disclosed above.

13. Claims 5, 8, 14-16, and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong.

Zhong et al. teach coating self-expanding metallic stents with a therapeutic substance in a polymer carrier with solvent (col. 2, lines 59-61 and 65; col. 6, line 52; col. 4, line 61). After application of the coating solution, Zhong teaches directing a gas stream so that the gas stream impinges on the surface of the stent and then the solvent is allowed to evaporate (col. 4, lines 37 and 52). While Examiner recognizes that the use of the gas stream in the method of Zhong is primarily used to remove excess coating material from the stent, it is Examiner's position that said gas stream also inherently induces evaporation of the solvent, as required by claim 5. Because Zhong teaches that the solvent is "allowed to evaporate", it appears that said solvent is readily evaporated. Thus, an active flow of gas over such a solvent will inherently start or induce the evaporation thereof. Additional inherent benefits, such as evaporation, of an old

process, such as using gas to impinge on a substrate, is not patentable. The mere observation of still another beneficial result of an old process cannot form the basis of patentability. *Allen et al. v. Coe*, 57 USPQ 136 ; *In re Maeder et al.* 143 USPQ 249.

In regard to claim 8, Zhong teaches spraying the coating solution of his invention (col. 3, line 34).

In regard to claims 15 and 16, Zhong teaches the use of radio chemicals and anti-proliferative agents as the therapeutic agent (col. 3, line 23). The antiproliferative of Zhong may be Taxol (col. 7, line 26), which is a paclitaxel chemical, as required by Appliant.

In regard to claim 20, the stent of Zhong appears from the Figures to be "at least partially expanded".

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan.

Fan teaches that which is disclosed above but fails to teach a suitable time and flow speed of applying his pre-heated gas to the coated substrate. A time and flow speed are inherently selected to perform the method of Fan. Selection of a length of time to dry with the gas and a flow speed of the gas would have been determined by one of ordinary skill based on the desired speed and degree of drying. It would have been obvious to one having ordinary skill in the art to have determined the optimum value of these cause effective variables through routine experimentation in the absence of a showing of criticality in the claimed variable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

16. Claims 6, 9-13, 17-18, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong.

Zhong teaches that which is disclosed above, but fails to teach repeating the coating step and gas impinging step to form a coating of desirable thickness or weight, as required by claim 6.

It is the Examiner's position that it would have been obvious to one of ordinary skill in the art to repeat the method of Zhong until the desirable or optimum coating thickness is obtained. It would have been obvious to coat with one thick layer or two thinner layers with the expectation of similar, successful results. In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially

identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959.

In regard to claims 9 and 10 requiring specific flow rates and duration of coating the implantable device with the coating composition, Zhong teaches that which is disclosed above. While Zhong teaches spraying the coating composition, he fails to teach the flow rate or duration of the coating supply. It would have been obvious to an ordinary artisan to select the quantity of coating composition to be applied per unit time and coating duration time to achieve a desired coating weight or thickness. Based on a given viscosity of the solution, type of nozzle used, and temperature of the solution, etc., one of ordinary skill would have selected appropriate flow rates and times to achieve a desired result. It would have been obvious to one having ordinary skill in the art to have determined the optimum value of a cause effective variable such as this through routine experimentation in the absence of a showing of criticality in the claimed variable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

In regard to claim 11 requiring a temperature for the gas, Examiner notes that the range required by Applicant overlaps room temperature. Because Zhong does not teach a temperature for the gas, it is Examiner's position that such a variable is not critical in the method of Zhong. Therefore one of ordinary skill in the art would have been expected to choose a suitable temperature to perform the method of Zhong or to simply use room temperature gas, which lies within Applicant's range.

In regard to claims 12-13, Zhong fails to teach the duration and flow speed of the gas. It is Examiner's position that optimization of these variables would have been obvious to one of ordinary skill in the art for the same reasoning as applied in the Fan rejection.

Regarding claims 17-18, Zhong teaches movement of the tool used to impinge the gas onto the stent. Figure 5 shows that the tool may be rotated or moved along the linear direction of the longitudinal axis of the stent. Claims 17 and 18 require that the stent be rotated or moved linearly, but it is the Examiner's position that moving the stent relative to the gas tool is interchangeable with moving the gas tool relative to the stent. All movement is relative. Therefore it would have been obvious to modify the method of Zhong to move the stent relative to the tool with the expectation of achieving successful results similar to those achieved by moving the tool relative to the stent.

Regarding claims 22-23, it is Examiner's position that room temperature gas, as taught above, is relatively "warm" as required by Applicant. Repetition of the processing steps as required in claim 23 would have been obvious to one of ordinary skill in the art for those reasons outlined above in regard to claim 6.

17. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Fan.

Zhong teaches that which is disclosed above including spraying a stent with a polymer, solvent, and optionally an active agent, followed by applying gas onto the stent, which inherently removes the solvent from the composition to form a coating on the stent. Zhong does not specifically teach that the gas is "warm".

Fan teaches that which is disclosed above including directing a stream of preheated gas onto an implantable device coated with polymer in solution to evaporate the solvent. Since Zhong and Fan teach directing streams of gas onto coated, wet medical implants and Fan teaches that such a stream of gas is preheated, Fan would have reasonably suggested preheating the gas stream of Zhong. It would have been obvious to one of ordinary skill in the art to use the teachings of Fan in the method of Zhong to provide Zhong with a heated gas that would initiate faster evaporation of the solvent to produce Zhong's desired dried product.

18. Claims 1-4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Pham et al.

Zhong teaches that which is disclosed above including spray-coating a polymer solution onto a metal medical device, followed by evaporation of the solvent to yield a dry coating.

Pham teaches pre-heating a metal substrate which to be spray-coated with a coating solution to hasten solvent evaporation to yield a dry coating more quickly.

Since Zhong and Pham teach spraying a solution onto metal articles and evaporating the solvent to obtain a dry final product and Pham teaches pre-heating the substrate to

hasten solvent evaporation, Pham would have reasonably suggested pre-heating the substrates of Zhong. It would have been obvious to one of ordinary skill in the art to use the teachings of Pham in the method of Zhong to increase the speed of evaporation in the method of Zhong, saving time and, thus, money.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tseng et al. teach the interchangeability of coating a pre-heated stent versus heating a coated stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
June 24, 2002

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